EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF ILLINOIS

J.F. a minor by MICHELLE LEAL
individually as parent and
next friend of J.F.

Plaintiffs,

vs.

CIVIL ACTION
NO. 14-cv-847-NJR

ABBOTT LABORATORIES, INC.,

Defendant.

DEPOSITION OF

GODFREY P. OAKLEY, JR., M.D.

August 4, 2015

10:00 a.m.

Suite 1400

1201 West Peachtree Street, NW

Atlanta, Georgia

Richard Bursky, RMR, CRR, CCR-2509

Q. In 1982 had you ever consulted with -- prior to 1982, had you ever consulted with the FDA about anything, any information that should or should not have been included in the prescription pharmaceutical label?

A. We certainly did research that the FDA depended on, but I do not remember having been asked or actually having given them advice on that.

Q. As of 1982, prior to the Depakote information coming out from Dr. Robert in late summer, early fall, had you ever offered anyone a professional opinion on the data or information that should or should not have been included in any prescription pharmaceutical label?

MS. LOOCKE: Objection, form.

A. I don't remember the exact timeframe, but we were very active in discussions about how Accutane should be regulated and we certainly had people from the CDC testify at those hearings. And we thought it needed to be more constrained in its use and decreasing the likelihood for pregnancy. So in that context we did make suggestions like that.

Q. You used the term "we" a couple times. I want to focus on just you, okay? Did you, prior to the fall of 1982, ever offer anyone a professional opinion concerning the informational contents of a prescription

A. I believe that to be correct.

Q. (By Mr. MacWilliams) Were you familiar in 1982 or 1983 with the regulations governing what should be included in a prescription pharmaceutical label?

MS. LOOCKE: Objection, form.

MR. MacWILLIAMS: What is your objection?

MS. LOOCKE: Was he familiar with the regulations?

MR. MacWILLIAMS: Yes.

MS. LOOCKE: It is outside the scope of what he said he's here to testify about.

MR. MacWILLIAMS: Okay.

Q. (By Mr. MacWilliams) You can answer, Doctor.

A. Sorry, the question again, please.

(Whereupon, the record was read by the reporter as requested.)

MS. LOOCKE: Same objection.

A. I guess I am certainly familiar in a general way with the process of getting a drug approved and the clinical trials and so on. And I know that there has to be a label as part of the approval process and the marketing process. I know that is sort of general in nature. The details of that, I am not aware of.

Q. So my question was: Were you familiar with the regulations that govern the contents of a

prescription pharmaceutical label?

MS. LOOCKE: Objection, form.

A. I don't think I have read those.

Q. (By Mr. MacWilliams) Ever?

A. I read the Kefauver hearings which provided the basis for those, but I don't think I actually read the regs afterwards.

Q. Do you even know what the lawyers call where those regulations are maintained?

A. You mean like the Federal Register?

Q. I don't know, are they in the Federal Register?

A. They usually are in the Federal Register to begin with, I think, certainly recommendations are there, proposed regs often go there.

Whether all the drug regs go there or not, I don't know, but other regulations go in the, in the Federal Register, so it is open to the public.

And I assume they are codified in a law, and I don't remember, is it Volume 42 something or other? But I really don't know.

Q. Prior to 1983 had you ever consulted with a prescription pharmaceutical manufacturer or marketer about the contents of a prescription pharmaceutical label?

A. No.

Q. Prior to 1983 had you ever consulted with anybody else, any other entity besides FDA or a manufacturer or marketer about that informational content of a prescription pharmaceutical label?

A. No.

MR. MacWILLIAMS: And I don't mean to be pugnacious about this, may I ask counsel, at what point in time do you propose is the cutoff after which he will not be offering opinions about what should or shouldn't have been in the label? Do I have to do this exercise from 1982 up to 2015 or is he limited just to 1982?

MS. LOOCKE: His report specifically references the 1982 Dear Doctor Letter and the accompanying package insert.

MR. MacWILLIAMS: Okay. So not after 1982?

MS. BRAHMBHATT: No.

MS. LOOCKE: Right, correct.

Q. (By Mr. MacWilliams) Doctor, the 1982 Dear Doctor Letter that is referenced in your report -- I am just looking to see if my copy has a date on it, I apologize if it does not.

Are you familiar with the sources of law that govern what should or should not be included in a Dear

Doctor Letter as of December 1982?

A. No.

Q. Is it your view that the CDC had any jurisdiction, if you will, over the contents of that Dear Doctor Letter?

A. I think the CDC and the people working at the CDC would be interested in that the risks that we had found were communicated and whether it was easily understood, that would be our interest in that.

Q. I didn't ask about your interest, I asked about your jurisdiction.

A. I don't think we have any jurisdiction on drug labeling.

Q. How about the Dear Doctor Letter?

A. As far as I know, no.

Q. I don't want to get bogged down in the legal niceties of jurisdiction. Did CDC have any authority to offer a definitive view of what should or shouldn't have been in that Dear Doctor Letter?

A. Well, the CDC's mission is to protect the public health, and in doing that certainly we would have some interest in seeing that that, that whatever the intervention was, that it accomplished the mission which was to decrease the exposure to this drug.

And I am sure that people can debate about

that suggests that they would have gotten any different number had they done that for spina bifida at any time between 1982 and 1996?

MS. LOOCKE: Objection.

A. It is always tough to predict that, that's why you do the study, to see if in fact you get a similar or different number. And, of course, there is the data from, from the Dutch people that found the number that was between five and six percent. I don't know what would have happened if there had been a study that big in 1982 or 1989 or whenever, because it wasn't done.

Q. (By Mr. MacWilliams) Are there any statistical indicators, are there any data, is there anything that you can point to and say that if Abbott had been tracking the data necessary to generate that number between 1982 and 1996 when Dr. Holmes started doing it, that there would have been something different about that data set that would have generated a number different, a range different than one to two percent?

A. I mean, until the study is done I don't know.

Q. You can't do it now, right?

A. You have to do the study, right?

Q. You can't do it now?

A. If you had 10,000 as opposed to 147, what would it look like? All sorts of things that would be

AFTERNOON SESSION

1:25 p.m.

MR. MacWILLIAMS: Back on the record.

Q. (By Mr. MacWilliams) Dr. Oakley, I neglected in my litany of what-do-you-know-about-this questions to ask you, have you ever been accepted by any court anywhere as an expert witness on the issue of what should or should not be in a prescription pharmaceutical drug label?

A. I don't think so.

Q. Have you ever authored or published anything on that topic?

MS. LOOCKE: Objection, form.

Q. (By Mr. MacWilliams) Other than your report and your supplemental report in this case?

A. I think the review article we did with Lammer and Samren must have talked about, you know, limiting the use of the drugs to women who actually needed it, and talking to your doctor about whether there is a better and that sort of thing.

Q. What review article was that?

A. It is one we have had before I think, it is Lammer is the first author.

Q. What year?

A. Like '86, I think, something like that.

Q. Did that specifically mention the labeling considerations?

A. I don't think so. I think it more, in the general idea of, just a review of valproic acid and women should try to get off of it if they could before they got pregnant, it they got pregnant prenatal diagnosis.

Q. I think you will agree with me that there is nothing in your October 1, 2014 report that says anything about what should or should not have been in the Depakote label as of 1982, correct?

MS. LOOCKE: Objection, form.

A. I believe that to be correct.

Q. (By Mr. MacWilliams) On Page 1 of your June 19, 2015 report it is written: "I conclude that this risk is high enough and serious enough that Abbott should have taken steps to limit the use of valproic acid to the absolute minimum number of women of reproductive age and to minimize pregnancies among women taking valproic acid."

What should they have done in your opinion to accomplish those goals?

A. Well, they could have, first of all, included the 20.6. They could have added to the package insert --

MS. LOOCKE: Yes, it is foremost in my mind.

MR. MacWILLIAMS: Got it.

Q. (By Mr. MacWilliams) Doctor, the reference to thalidomide at the Schmidt trial, the reference to the top three, did you have any discussions with anybody so far that we haven't talked about today that relate to that subject of, relating to the jury that Depakote was in the top three most teratogenic drugs on the market in the US?

MS. LOOCKE: Objection.

Q. (By Mr. MacWilliams) In preparation for the trial, any discussions you haven't already told me about?

MS. LOOCKE: Objection, form and scope.

A. Not that I am aware of.

Q. (By Mr. MacWilliams) How did you arrive at that list?

A. Based on my understanding of the causes of birth defects and it is obviously a -- it is my personal interpretation of those. I know that thalidomide is a terrible drug, taken off the market for many, many years and it is back on the market in very limited circumstances but it is back on the market.

And Accutane is another powerful cause of

Q. (By Mr. MacWilliams) 2002.

A. I don't remember when it came back on the market, it did come back on the market around that time but I don't remember exactly when.

Q. Do you know whether it is in the 2002 PDR?

A. I do not know that.

Q. Did you have anybody review the 2002 PDR for you in support of offering your opinion that of all the drugs in that, the thousands of drugs in that book that Mr. Williams was holding up, Depakote was in the top three most teratogenic?

MS. LOOCKE: Objection, form and scope.

A. I did not.

Q. (By Mr. MacWilliams) Did anybody from counsel side suggest to you that maybe the two others that you want to include in that list are thalidomide and Accutane or did you come up with that on your own?

A. I came up with that --

MS. LOOCKE: Objection, form and scope.

A. I came up with that on my own.

Q. (By Mr. MacWilliams) Have you ever heard of a drug called Tracleer?

A. No.

Q. Do you know whether, what pregnancy category it has been assigned by the FDA?